

JUN 12 2003

K031103

(2)

510(k) SUMMARY
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DATE: April 4, 2003

CONTACT PERSON: Linda K. Dillon
Chuck Lakel
Pasco Laboratories
12750 West 42nd Avenue
Wheat Ridge, Co 80033
303-423-9504

TRADE NAME OF DEVICE: Pasco MIC and MIC/ID Panels

COMMON NAME: Antimicrobial Susceptibility Test

CLASSIFICATION NAME: Class II Antimicrobial Susceptibility Test
Microbiology Panel #83

SUBSTANTIAL EQUIVALENCE:

In review of previous 510(k) notifications for the Pasco MIC and MIC/ID panel:
K011116, April 24, 2001 RE: ESBL Confirmatory Test; K010508, April 23, 2001 RE: ESBL Screen Test; K020331, March 20, 2002 RE: Ertapenem; K001953, August 10, 2000 RE: Amoxicillin; K001887, August 9, 2000 RE: Ampicillin; K001721, August 4, 2000 RE: Clarithromycin; K001612, July 18, 2000 RE: Linezolid; K001516, July 12, 2000 RE: Moxifloxacin; K992853, November 4, 1999 RE: Cefdinir; K992726, November 3, 1999 RE: Synercid (non-fastidious); K992717, November 2, 1999 RE: Synercid; K992646, October 19, 1999 RE: Penicillin; K992647, October 19, 1999 RE: Erythromycin; K992593, October 14, 1999 RE: Chloramphenicol; K992562, October 13, 1999 RE: Ceftriaxone; K992568, October 14, 1999 RE: Cefotaxime; K992507, October 18, 1999 RE: Trovafloxacin; K992546, October 12, 1999 RE: Meropenem; K992420, September 27, 1999 RE: Sparfloxacin; K992296, September 21, 1999 RE: Vancomycin; K992297, September 3, 1999 RE: Levofloxacin; K992143, September 16, 1999 RE: Clindamycin; K992108, September 3, 1999 RE: Cefepime; K992076, August 30, 1999 RE: Cefuroxime; K992059, August 30, 1999 RE: Imipenem; K992077, September 3, 1999 RE: Ofloxacin; K991925, August 20, 1999 RE: Amoxicillin/Clavulanic Acid; and K946126, January 17, 1995 RE: Detection of resistant pneumococci, the FDA has determined the Pasco panels to be substantially equivalent to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments.

The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug, and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of

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substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of, substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DESCRIPTION OF THE DEVICE:

Pasco Panels are used for quantitatively measuring the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms. Varying concentrations of antimicrobial agents (usually in two-fold dilutions) are dispensed into the Pasco microdilution panels and the panels are then frozen. Panels are thawed prior to use, inoculated with the test organisms, incubated the traditional 16-24 hours and panels are then observed for visible growth or color changes as described in the package insert.

The lowest concentration of each antimicrobial agent with no apparent visible growth of the test organism is recorded as the minimum inhibitory concentration (MIC). Changes in pH and production of specific metabolites from growth in biochemical substrates are interpreted as described in the package insert for conventional tubed media.

INTENDED USE FOR THE PASCO MIC AND MIC/ID PANELS:

PASCO MIC AND MIC/ID PANELS are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement or category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.

SUMMARY/CONCLUSION OF SUBSTANTIAL EQUIVALENCE TESTING:

Challenge strains, fresh clinical isolates, stock clinical isolates and QC strains were tested concurrently using both Pasco methodology and reference methodology in panels contained Ertapenem at concentrations ranging from 0.03 – 32 mcg/ml. Testing was conducted at three test sites.

Test results from 410 challenge and clinical *Staphylococci spp.* demonstrated an Essential Agreement (EA) of 98.3%. For the methicillin-susceptible *Staphylococci spp.*, the Category agreement (CA) was 100% with no very major, major or minor errors noted.

Test results of 574 challenge and clinical Enterobacteriaceae demonstrated an Essential Agreement (EA) of 99.6%. No major (M) or very major (VM) errors were observed. Category Agreement (CA) was acceptable at 99.4% with 5 random minor discrepancies, all of which were within EA.

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QC endpoints for the NCCLS recommended QC organisms (*S. aureus* ATCC 29213, *E. faecalis* ATCC 29212, *E. coli* ATCC 25922 and *P. aeruginosa* ATCC 27853) from panels using both the reference and test methodology were acceptable.

Reproducibility testing of 10 organisms at each site on three separate days in triplicate demonstrated inter-site reproducibility of MIC results of 100%. Intra-site reproducibility of MIC results was also 100% for all sites.

The results of the clinical testing, reproducibility testing and QC performance testing supports Substantial Equivalence as outlined in the FDA document "Class II Special Controls Guidance Document: Antimicrobial Susceptibility Test (AST) Systems; Guidance for Industry and FDA.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JUN 12 2003

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Ms. Linda K. Dillon
R&D Manager
BD Diagnostics Systems
Pasco Laboratories
12750 W. 42nd Avenue
Wheat Ridge, CO 80033-2440

Re: k031103
Trade/Device Name: PASCO MIC and MIC/ID Panels
Ertapenem, 0.03-32 µg/ml
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test
Regulatory Class: Class II
Product Code: JWY
Dated: April 4, 2003
Received: May 14, 2003

Dear Ms. Dillon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

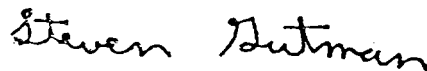
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive, slightly slanted style.

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K031103

Device Name: **PASCO MIC and MIC/ID Panels**

Indications For Use: Inclusion of Ertapenem

Pasco MIC and MIC/ID panels are used for quantitatively measuring (with the exception of the Breakpoint/ID panel which provides qualitative measurement of category results) the susceptibility of rapidly growing aerobic and facultative anaerobic bacterial pathogens to a battery of antimicrobial agents and determining the biochemical identification of those organisms.

This 510(k) notification is for the addition of the antimicrobial Ertapenem at concentrations of 0.03 – 32 mcg/ml to Pasco Panels. Ertapenem has been shown to be active *in vitro* against most strains of microorganisms listed below, as described in the FDA-approved package insert for this antimicrobial.

Active *In Vitro* and in Clinical Infectious Against:

Aerobic Gram-positive microorganisms

Staphylococcus aureus (methicillin-susceptible strains only)

Aerobic Gram-negative microorganisms

Escherichia coli

Klebsiella pneumoniae

Active *In Vitro* but their clinical significance is unknown

Aerobic Gram-negative microorganisms

Citrobacter freundii

Citrobacter koseri

Enterobacter aerogenes

Enterobacter cloacae

Klebsiella oxytoca (excluding ESBL producing strains)

Morganella morganii

Proteus mirabilis

Proteus vulgaris

Serratia marcescens

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Sally J. Delgado for K. Poole
Division Sign-Off

Division Sign-Off

Concurrence of CDRH, Office of Device Evaluation (ODE)

**Office of In Vitro Diagnostic Device
Evaluation and Safety**

Prescription Use 510(k) OR 03 Over-The-Counter Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)